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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

VIVLEMORE, TRACY ANN

ART UNIT PAPER NUMBER

1635

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/944,326

Applicant(s)

GLEAVE ET AL.

Examiner

Tracy Vivlemore

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 17, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 12-19 and 21-27 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 17, 18 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 12-16 and 22-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

The claim amendment filed on October 6, 2004 does not comply with the requirements of 37 CFR 1.121(c) because the claim identifiers are not correct for all claims. Claims 4, 5, 17, 18 and 21 should be indicated as "withdrawn", not "original". This omission must be corrected in any future communications, failure to do so will result in any response to this action being considered non-responsive.

Response to Arguments

Double Patenting

1. Claims 1-3, 12-16 and 22-27 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting for the reasons outlined in the previous office action. Applicant's arguments filed June 17, 2004 have been fully considered but they are not persuasive. Applicant asserts that as the conflicting, co-pending application (the '794 application) is the later filed application a two-way test for obviousness is required. This is not true. MPEP 804 requires a two-way test for obviousness only in situations where the claims conflict with those of a patent which has issued from a later filed application. MPEP 804 (II) (B)(1)(a) states

"even if the application at issue is the earlier filed application, only a one-way determination of obviousness is needed to support a double patenting rejection in the absence of a finding of: (A) administrative delay on the part of the Office causing delay in prosecution of the earlier filed application; and (B) applicant could not have filed the conflicting claims in a single (i.e., the earlier filed) application."

2. As the conflicting claims are from a pending application, not a patent, the one-way test of obviousness applied by the examiner in the previous office action is proper and the rejection of record is maintained.

Claim Rejections - 35 USC § 102

3. Claims 1, 2, 22, 23 and 27 remain rejected under 35 USC 102 (b) as being anticipated by Sensibar et al. Applicant's arguments filed June 27, 2004 have been fully considered but they are not persuasive. Applicants assert that Lipofectin is not a suitable carrier for a pharmaceutical composition as it is not suitable for *in vivo* use in humans. Lipofectin is considered to be suitable for pharmaceutical compositions, as evidenced by US patent 5,998,148, which states at column 2, lines 56-62,

"Further provided are methods of treating an animal, particularly a human...by administering a therapeutically or prophylactically effective amount of ... the antisense compounds or compositions of the invention"

and at column 22, lines 50-57:

"Agents that enhance uptake of oligonucleotides at the cellular level may also be added to the pharmaceutical and other compositions of the present invention. For example, cationic lipids, such as lipofectin ... are also known to enhance the cellular uptake of oligonucleotides."

4. Additionally, the instant specification teaches on page 9 that lipid carriers such as those described in US patents 5,855,911 and 5,417,978 are pharmaceutically acceptable carriers and incorporates the disclosures of these patents by reference. The '911 patent discloses at column 1, lines 38-44:

"Cationic lipids, such as Lipofectin, have also been used to deliver phosphodiester or phosphorothioate oligonucleotides. An electrostatic interaction is formed between the cationic lipids and the negatively charged phosphodiester or phosphorothioate oligonucleotides, which results in a complex that is then taken up by the target cells."

5. The claims have been amended to recite "a carrier suitable for human administration for providing the oligonucleotide to a mammalian subject". The claims as amended do not limit use of the composition to humans, the intended recipients are mammals.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

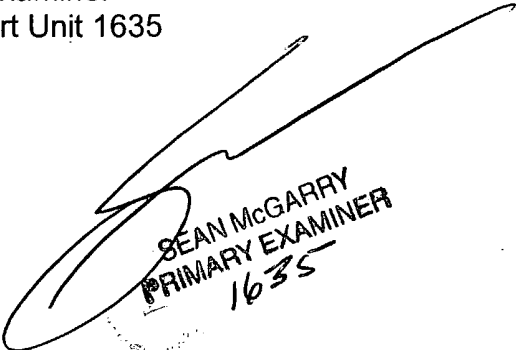
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
October 26, 2004


SEAN McGARRY
PRIMARY EXAMINER
1635